

REMARKS

Claims 1-30 are presently pending in the case. Claims 5, 10, 13, 14, 18, 20 and 26 have been amended. Claims 18 and 20 have been amended merely to correct a typographical error. Support for the amendments can be found throughout the specification and claims as originally filed. Reconsideration of the present case in view of the amendments and remarks herein is requested.

Claim rejections under 35 USC §102

The Examiner rejected claims 1-21 under 35 USC §102(b) as being anticipated by Published PCT Application WO 92/07599 to Smith et al (hereinafter Smith et al). The rejection is traversed.

Smith et al does not anticipate independent claim 1, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 1 is to an aerosolization device comprising, inter alia, a metering valve that is moveable into a container to an actuated position so that a predetermined amount of the pharmaceutical formulation may be released and a contact member that is moveable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when in the first position and is unable to contact the contact member when in the second position. This positively recited feature is not disclosed by Smith et al. Smith et al does not disclose a contact member moveable between a first and second position wherein the metering valve is able to contact the contact member in the first position and unable to contact the member in the second position. Since Smith et al does not disclose each and every feature set forth in claim 1, it does not anticipate the claim.

The Examiner's contentions taken in the Office Action of June 28, 2007 are not sufficient to justify a rejection under 35 U.S.C. §102(b). For example, the Examiner

posits on page 2 of the Office Action that element 18 of Smith et al satisfies the contact member limitation of claim 1. This is not correct. Element 18 of Smith et al, as shown in Figure 1 and discussed on page 19 of Smith et al, is a "blocking member" that prevents downward movement of a canister (4) thereby preventing actuation of a valve (6). At no time is the valve able to contact the blocking member of Smith et al. Since claim 1 recites that the valve is "able to contact the contact member when in the first position" and since the blocking member (18) of Smith et al does not meet this limitation, Smith et al does not anticipate claim 1.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of claims 2-4 which depend from claim 1 and are not anticipated by Smith et al for at least the same reasons as claim 1.

Independent claim 5 is also not anticipated by Smith et al. Claim 5 is to an aerosolization device comprising, inter alia, a metering valve and a contact member, the contact member having a first configuration and a second configuration, wherein a portion of the metering valve is able to contact the contact member when in the first configuration in a manner which allows the metering valve to be moved to the actuated position and wherein a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuated position. Smith et al does not disclose a device as set forth in claim 5. Smith et al does not disclose a contact member having first and second configurations and specifically does not disclose a second configuration wherein the metering valve is able to contact the contact member in a manner which does not allow the metering valve to be moved to the actuated position. Accordingly, Smith et al does not anticipate claim 5.

Applicant requests withdrawal of the rejection of claim 5 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of claims 6-9 which depend from claim 5 and are not anticipated by Smith et al for at least the same reasons as claim 5.

In addition, Smith et al does not anticipate independent claim 10. Claim 10 is to an aerosolization device comprising, inter alia, a metering valve and a contact member, the contact member having a first condition and a second condition, wherein a portion of the metering valve is able to contact the contact member when in the first condition in a manner which allows the metering valve to be moved to the actuated position and wherein a portion of the metering valve is able to contact the contact member when in the second condition in a manner which does not allow the metering valve to be moved to the actuated position. Smith et al does not disclose a device as set forth in claim 10. Smith et al does not disclose a contact member having first and second conditions wherein in the second condition, the metering valve is able to contact the contact member in a manner which does not allow the metering valve to be moved to the actuated position. Accordingly, Smith et al does not anticipate claim 10.

Applicant requests withdrawal of the rejection of claim 10 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of claims 11-17 which depend from claim 10 and are not anticipated by Smith et al for at least the same reasons as claim 10.

Furthermore, independent claim 18 is not anticipated by Smith et al. Claim 18 is to an aerosolization device comprising, inter alia, a metering valve, a container, and a contact member, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member and may not be actuated when the metering valve and/or the container is unable to contact the contact member. Smith et al does not disclose that which is claimed in claim 18. In fact, Smith et al operates in an opposite manner to that which is claimed. In Smith et al, the metering valve **may not be** actuated when the canister (4) contacts the blocking member (18) and **may be** actuated when the canister is unable to contact the blocking member. Therefore, Smith et al discloses a system different from that which is claimed in claim 18 and does not anticipate the claim.

Applicant requests withdrawal of the rejection of claim 18 under 35 U.S.C.

§102(b). In addition, Applicant requests withdrawal of claim 19 which depends from claim 18 and is not anticipated by Smith et al for at least the same reasons as claim 18.

Smith et al does not anticipate independent claim 20, either. Claim 20 is to an aerosolization device comprising, inter alia, a container, a metering valve, and a contact member, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member in a rigid configuration and may not be actuated when the metering valve and/or the container is unable to contact the contact member in a rigid configuration. Smith et al does not disclose a device that may not be actuated when a metering valve and/or container is unable to contact a contact member in a rigid configuration.

Applicant requests withdrawal of the rejection of claim 20 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of claim 21 which depends from claim 20 and is not anticipated by Smith et al for at least the same reasons as claim 20.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 22-30 under 35 USC §103(a) as being unpatentable over Smith et al. The rejection is traversed.

Smith et al does not render independent claim 22, for example, unpatentable. Claim 22 is to a method of controlling the operation of an aerosolization device comprising, inter alia, positioning a contact member in a first position where the contact member may contact the metering valve and/or the container to allow the metering valve to be moved to the actuated position and positioning the contact member in a second position where the metering valve may not be moved to the actuated position. Smith et al does not disclose, teach or suggest the claimed method. Smith et al, in contrast, teaches the use of a blocking member (18) that is positioned to contact the canister (4) to prevent actuation of the device. Thus, Smith et al teaches the opposite of that which is claimed, namely that the contact member is positioned in a first position to

allow the metering valve and/or container to contact the contact member to allow actuation. Since Smith et al does not disclose or teach all that is claimed and since the Examiner has not provided any explanation as to how it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith et al in a manner that would result in the claimed method, there is no prima facie case established and claim 22 is not rendered unpatentable under 35 U.S.C. §103(a).

Applicant requests withdrawal of the rejection of claim 22 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of claims 23-25 which depend from claim 22 and are not rendered unpatentable by Smith et al for at least the same reasons as claim 22.

Smith et al also fails to render independent claim 26 unpatentable under 35 U.S.C. 103(a). Claim 26 is to a method of controlling the operation of an aerosolization device comprising, inter alia, configuring a contact member in a first configuration wherein the contact member may contact a metering valve to allow the metering valve to be moved to an actuated position and configuring the contact member in a second configuration wherein the metering valve may contact the contact member but may not be moved to the actuated position. Smith et al does not disclose, teach or suggest the claimed method. Smith et al does not disclose a second configuration wherein a metering valve may contact a contact member but may not be moved to an actuated position. Since Smith et al does not disclose or teach all that is claimed and since the Examiner has not provided any explanation as to how it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith et al in a manner that would result in the claimed method, there is no prima facie case established and claim 26 is not rendered unpatentable under 35 U.S.C. §103(a).

Applicant requests withdrawal of the rejection of claim 26 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of claims 27-30 which depend from claim 26 and are not rendered unpatentable by Smith et al for at least the same reasons as claim 26.


Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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